

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

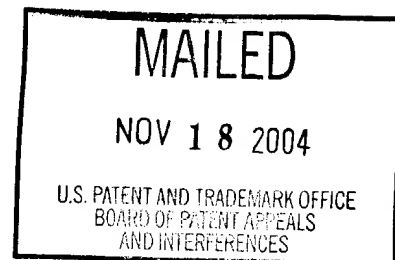
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JITENDRA P. PATEL, YESHWANT D. SANZGIRI,
JOHN M. LIPARI, and THOMAS L. REINLAND

Appeal No. 2004-1731
Application No. 09/524,113

ON BRIEF



Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3, 7-12, and 19, which are the pending claims in the application.

Claims 1 and 19 are illustrative of the subject matter on appeal and are reproduced below:

1. A composition consisting essentially of a fibrate dissolved in at least one oil with one emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid exthoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

19. A composition consisting of a fibrate dissolved in at least one oil with one emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

The examiner relies on the following reference:

Lacy et. al. (Lacy)	5,645,856	Jul. 8, 1997
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GROUND OF REJECTION

Claims 1, 3, 7-12 and 19 stand rejected under 35 USC §103(a) as being unpatentable over Lacy.

We affirm.

CLAIM GROUPING

Appellants set forth two claim groupings. Brief, page 2. According to appellants (*id.*), for the first group, claims 1, 3 and 7-12 stand or fall together. Since these claims stand or fall together, we limit our discussion to representative independent claim 1. Claims 3 and 7-12 will stand or fall together with claim 1. *In re Young*, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991). Claim 19 stands or falls alone.

Accordingly, we limit our discussion to representative independent claims 1 and 19.

DISCUSSION

According to the examiner (Answer, bridging paragraph, pages 4-5), Lacy "teaches a carrier system for a hydrophobic drug (including finofibrate [sic])

composition comprising (a) a digestible oil ... (b) a pharmaceutically acceptable surfactant comprising a hydrophilic ... and a lipophilic surfactant....” While the examiner finds (Answer, page 5) Lacy does not “teach an emulsion composition consisting essentially of fenofibrate with the claimed oil and emulsifiers,” the examiner finds such a composition would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.¹

Claim 1:

Appellants’ claim 1 is drawn to a composition consisting essentially of:

1. a fibrate dissolved in
2. at least one oil with
3. one emulsifier, selected from a Markush grouping of emulsifiers.

According to claim 1, the resulting mixture of a fibrate, oil and emulsifer forms an emulsion upon dilution with an aqueous phase.

It is appellants’ position (Brief, page 4) that “Lacy discloses a carrier for hydrophobic drugs comprising a digestible oil and a pharmaceutically acceptable surfactant component for dispersing the oil in vivo.” According to appellants (id.), “[t]he surfactant component [of Lacy’s composition] comprises a hydrophilic surfactant component, that does not substantially inhibit the lipolysis of the oil....” In contrast to Lacy, appellants argue (Brief, bridging paragraph, pages 4-5) “[t]he emulsifiers used in the present invention do not exhibit or demonstrate the property of not substantially inhibiting the lipolysis of the oil.... [T]here is no requirement [in their claim] for a surfactant that does not substantially inhibit lipolysis.” According to appellants’ (Brief, page 5), “[t]he inclusion of a surfactant

¹ We find no argument on this record that the resulting mixture of Lacy’s components does not form an emulsion upon dilution with an aqueous phase. Accordingly, we find that appellants’ have conceded this fact.

that does not substantially inhibit lipolysis of an oil is an important property of Lacy's compositions ... this is NOT a property of the presently claimed invention."

Upon review of Lacy, we find that Lacy discloses (column 3, lines 39-45) the invention "in its broadest aspect provides a carrier system for a hydrophobic drug which comprises: (a) a digestible oil, and (b) a pharmaceutically acceptable surfactant for dispersing the oil in vivo upon administration of the carrier system, said surfactant comprising a hydrophilic surfactant component...." As we understand Lacy's disclosure, Lacy overcomes the disadvantages of using drug in oil alone by including a hydrophilic surfactant to the drug in oil composition. However, as Lacy points out (column 3, lines 50-52), the majority of hydrophilic surfactants "will inhibit the lipolysis of the digestible oil component." Therefore, to overcome the inhibitory effect of the hydrophilic surfactant, Lacy's composition must also include a lipophilic co-surfactant. Lacy, column 3, lines 52-55.

Accordingly, as we understand Lacy's disclosure, Lacy's composition includes four components,

1. a hydrophobic drug (such as fenofibrate², see e.g., Lacy, column 12, line 23),
2. a hydrophilic surfactant (e.g., castor oil or hydrogenated castor oil ethoxylates, see Lacy, column 7, line 10)
3. a digestible oil, and
4. a lipophilic surfactant.

In contrast, as discussed above, appellants' claimed invention includes three components,

1. a hydrophobic drug (a fibrate, such as fenofibrate³),

² We find no argument on this record that Lacy does not teach fenofibrate. Accordingly, we find that appellants' have conceded these facts.

2. one emulsifier (e.g., castor oil and hydrogenated castor oil ethoxylates, see appellants' claim 1), and
3. at least one oil.

We note that despite appellants' arguments to the contrary⁴, Lacy's hydrophilic surfactant appears to be the same as appellants' castor oil and hydrogenated castor oil ethoxylates emulsifier. Therefore, as we understand the issue on appeal, the question is whether Lacy suggests a composition wherein either the lipophilic surfactant is not necessary, or the lipophilic surfactant can serve as digestible oil.

In this regard, we note that Lacy carves out an exception to the use of digestible oils. Specifically, Lacy discloses (column 4, lines 1-5), "[i]f the lipophilic surfactant is itself a digestible oil, or can serve as the source of lipolytic products, then in a modification of the preferred carrier system a separate digestible oil component may be omitted...." At column 6, lines 15-17, Lacy specifically discloses that the lipophilic surfactants listed at column 4, line 39 through column 5, line 25, "are capable of serving as the digestible oil component...."

Appellants' claim 1 does not define a specific oil for use in the claimed composition. In this regard, we note that appellants' specification (page 5, lines 13-17) discloses "[s]uitable oils include, but are not limited to, any pharmaceutically acceptable oil...." Accordingly, we find that the compounds set forth at column 4, line 39 through column 5, line 25, which "are capable of

³ Appellants disclose (specification page 16-22), fenofibrate "is part of a lipid-regulating agent class of compounds commonly known as fibrates...."

⁴ See e.g., Brief, page 4, wherein appellants argue "[t]he emulsifiers used in the present invention do not exhibit or demonstrate the property of not substantially inhibiting the lipolysis of the oil. Accord Reply Brief, page 3.

serving as the digestible oil component...” of Lacy’s invention meet the oil limitation set forth in appellants’ claim 1.

Thus, we agree with the examiner that Lacy teaches a composition consisting essentially of a fibrate (fenofibrate), dissolved in at least one oil, with one emulsifier (castor oil or hydrogenated castor oil ethoxylates), as set forth in appellants’ claim 1, that would form an emulsion upon dilution with an aqueous phase. We are not persuaded that the components set forth in the invention of Lacy are different from the components set forth in appellants’ claimed invention simply because they use different descriptors⁵, or because appellants’ claim does not require the emulsifier to exhibit or demonstrate the property of not essentially inhibiting the lipolysis of oil as described in Lacy’s disclosure (e.g., column 3, lines 50-55).

On reflection, we find no error in the rejection of record. Accordingly, we affirm the rejection of claim 1 under 35 USC §103(a) as being unpatentable over Lacy. As discussed supra claims 3, and 7-12 fall together with claim 1.

Claim 19:

As illustrated above, claim 19 differs from claim 1 only by the use of a different transitional phrase in the preamble - “consisting of” (claim 19) vs. “consisting essentially of” (claim 1). Appellants’ only argument with regard to claim 19 is to explain the difference between the transitional phrases “consisting of” and “consisting essentially of”. See Brief, page 3. While we agree with appellants’ explanation of the difference between these two transitional phrases,

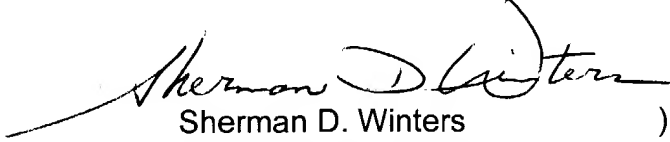
⁵ For example, Lacy’s use of the term hydrophilic surfactant vs. appellants’ use of the term emulsifier, to describe castor oil or hydrogenated castor oil ethoxylates.

for the foregoing reasons we are not persuaded that the use of the transitional phrase "consisting of" in appellants' claim 19 removes the rejection over Lacy.

Accordingly, for the same reasons that apply to claim 1 discussed above, we affirm the rejection of claim 19 under 35 USC §103(a) as being unpatentable over Lacy.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



Sherman D. Winters
Administrative Patent Judge


Toni R. Scheiner
Administrative Patent Judge

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Donald E. Adams
Administrative Patent Judge

ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK IL 60064-6008